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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,868	12/09/2003	Ruchika Singhal	1023-330US01	6697

28863 7590 07/28/2005  
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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/731,868

Applicant(s)

SINGHAL ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14 and 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10-28-04, 6-20-05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I(A) and II (BB, CC, and GG) in the reply filed on April 11, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicant stated claims 1-13 and 15-17 were drawn to the elected invention. However, claim 13 is drawn to an unelected species (figure 11, paragraph 0040).
3. Claims 13, 14, 18-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 11, 2005.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 5-10, 12, 15, 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Fischell et al. US PN 6,427,086.

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6. Fischell et al. discloses in figures 21,26,27 and columns 31-35 a method of implanting an implantable medical device comprising creating a pocket and recess in the scalp for the implant which comprises a periphery having an angle of approximately 135 degrees, leads extending through bore holes in the skull, bone screw anchors, and means for adjusting the contour of the device to conform to the skull (RTV silastic lines 51-52 of col. 35).

7. Claims 1-3,5-7,9,10,12,15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Berrang et al. US PN 6,648,914.

8. Berrang et al. discloses in figures 1-3 and line 42 of col. 9 through line 25 of col. 14 a method of implanting an implantable medical device using local anesthetic comprising creating a pocket and recess in the scalp for the implant which comprises a periphery having an angle of approximately 135 degrees, leads, bone screw anchors, first and second module within housings partially covered by a flexible overmold, wherein the maximum thickness is between 4-8mm.

9. Claims 1-4,7,15 are rejected under 35 U.S.C. 102(e) as being anticipated by Berrang et al. US PUB2003/0109903.

10. Berrang et al. discloses in figures 1 and 25 and paragraphs 46-48,54-56, and 80 a method of implanting an implantable medical device comprising creating a pocket in the scalp for the implant which comprises leads, first and second module within

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housings partially covered by a flexible overmold, wherein the maximum thickness is approximately 6mm.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell US PN 6,427,086 or Berrang et al. US PN 6,648,914 or Berrang et al. US PUB 2003/0109903.

13. Each of Fishcell and Berrang et al. independently meet the limitations of claim 11 but lack the express written disclosure of suturing the flap over the implant to complete the implantation procedure. The Examiner hereby takes Official Notice that suturing a skin flap to complete a surgical procedure is well known in the art.

14. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to include the step of suturing the flap to close the incision.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number

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is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



WHM  
7-21-05



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